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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------------------|--------------|----------------------|-------------------------|------------------|
| 09/982,853 | 10/22/2001 | Avraham Shekalim | 2472/2 | 7675 |
| 75 | 10/08/2003 | EXAMINER | | |
| | RIEDMAN LTD. | KONTOS, LINA R | | |
| C/o Bill Polking Discovery Disp | | ART UNIT | PAPER NUMBER | |
| 9003 Florin Wa | у | 3763 | | |
| Upper Marlbord | o, MD 20772 | | DATE MAILED: 10/08/2003 | Y |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Application No. | | | | | | | | | | |
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| Examiner Lina Kontos 3763 - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after St. (b) MONTHS from the maining date of this communication If the period for reply sepecified above is test sheen thing (30) days, a reply within the adautory minimum of thing (30) days, a reply within the adautory minimum of thing (30) days will be considered firmally If the period for reply secreted by the Office later than the order with prevailed in apply and with secretic the communication If the period for reply secreted by the Office later than the maining date of this communication will be considered firmally If the period for reply the Office later than the maining date of the secretic secretic properties If the period for reply within the adautory definition to the communication If the period for reply within the adaption of the order with prevailed and secretic properties If the period for reply within the adaption of the order with prevailed and the period of the | | | Application No. | | Applicant(s) | Applicant(s) | | | | |
| Lina Kontos 3763 | | 055 - 4-45 - 0 | 09/982,85 | 3 | SHEKALIM, AVRA | SHEKALIM, AVRAHAM | | | | |
| - The MAILING DATE of this communication appears on the cover sheet with the correspondence address - Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Edensions of time may be voicible under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SX (b) MONTH(S) from the mailing date of this communication. If the period for reply specified above is less than thry (30) days, a reply within the statutory minimum of thirty (20) days will be considered timely. If the period for reply specified above is less than thry (30) days, a reply within the statutory minimum of thirty (20) days will be considered timely. If the period for reply specified above is less than thry (30) days, a reply within the statutory minimum of thirty (20) days will be considered timely. If the period for reply specified above is less than thry (30) days, a reply within the statutory minimum of thirty (20) days will be considered timely. If the period for reply specified above is less than three ments of the provision of the statutory minimum of thirty (20) days will be considered timely. Any reply received by the Office laster than three ments (30) and the statutory minimum of thirty (20) days will be considered timely. Any reply received by the Office is a reply within the statutory minimum of thirty (20) days will be considered timely. Any reply received by the Citical time is a reply within the statutory minimum of thirty (20) days will be considered timely. Any reply received the time of the minimum of the statutory minimum of thirty (20) days will be considered timely. Any reply received by the Office and the provision of the minimum of the provision of the provision of the calculation o | | Office Action Summary | Examiner | | Art Unit | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filled after St. (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire ST. (5) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire ST. (5) MONTHS from the mailing date of this communication. Failure to reply whith the set or extended period for reply will, by statutor, easier the application become MEADONED (35 U.S. C. § 133). Any reply received by the Office later than three monitals after the mailing date of this communication, even if timely filled, may reduce any earned patient term adjustment. See 37 CFR 1.74(b). Status Status Status 1) Seponsive to communication(s) filled on 28 July 2003. 2a) This action is FINAL. 2b) This action is non-final. 3) since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-21 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) 3-5.8.9.17-21 is/are objected to. 8) Claim(s) 3-5.8.9.17-21 is/are objected to. 8) Claim(s) 3-5.8.9.17-21 is/are objected to. 8) Claim(s) 3-5.8.9.17-21 is/are a publect of restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). 11) The orath or declaration is objected to by the Examiner. If approved, corrected drawing correction filled on is: a) approved by dis | | TI MANUNO DATE CHI | | | 1 | | | | | |
| THE MAILING DATE OF THIS COMMUNICATION. Edentions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTH'S from the mailing date of this communication. If the period for reply is specified above, is the sink hitty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, is the maximum statutory period will apply and will expire SIX (6) MONTH'S from the mailing date of this communication. Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any searned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 28 July 2003. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-21 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) 1-26.7 and 10-16 Is/are rejected. 7) Claim(s) 3-5.8.9.17-21 Is/are objected to. 8) Claim(s) 3-5.8.9.17-21 Is/are objected to. 8) Claim(s) 3-5.8.9.17-21 Is/are objected to. 10) The drawing(s) filed on is/are: a) cacepted or b) objected to by the Examiner. Application Papers 9) The specification is objected to by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. If approved, corrected drawings are required in reply to this Office action. 12) The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. §§ 119 and 120 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) Copies of the certified copies of the priority documents hav | Period fo | | ppears on the | cover sheet l | with the correspondence add | dress | | | | |
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| | * (| application from the International E | Bureau (PCT | Rule 17.2(a)) | | otage | | | | |
| a) The translation of the foreign language provisional application has been received | 14) 🗌 / | Acknowledgment is made of a claim for domes | stic priority ur | nder 35 U.S.C | C. § 119(e) (to a provisional | application). | | | | |
| 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121. | | | • | · | | | | | | |
| Attachment(s) | Attachmer | ut(s) | | | | | | | | |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4) Interview Summary (PTO-413) Paper No(s) 5) Notice of Informal Patent Application (PTO-152) 6) Other: | 2) Notic | ce of Draftsperson's Patent Drawing Review (PTO-948) | J • | 5) Notice of | | | | | | |

Art Unit: 3763

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,2,6,7,14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al.

Singh et al. teaches an infiltration indicator for an infusion system comprising a long rigid duct (column 2, line 20) with holes (column 2, line 22) which joins to the tubing of the infusion system (column 2, lines 37-39). Surround the duct is a closely fitting elastomeric tube (column 2, lines 24-25). When infiltration occurs, fluid flowing through the duct seeps out the holes, expanding the elastomeric tube (column 2, lines 30-32), and changing the status of electrical contacts, thus triggering an alarm (column 2, lines 57-59 and column 3, lines 16-23). In its normal unstressed state, tubing (20,21) normally abuts duct (16) (column 3, lines 3-4).

It would have been obvious to one skilled in the art at the time of the invention to have the tubing expand when pressure reaches about 1atm as this solely depends on the material used for the tubing. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

2.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. as applied to claim 1 above, and further in view of Atkins et al.

Application/Control Number: 09/982,853

Art Unit: 3763

Signh et al., as described above, teaches a infiltration indicator for use with an infusion

pump system

Atkins teaches a method for detecting fluid infiltration during the administration of

intravenous fluids comprising sensors and an alarm system wherein the entirety of the system

can be powered by battery (column 5, line 50). Tissue infiltration is indicated by the sounding of

an alarm, or a visible light (column 5, lines 31-34).

It would have been obvious to one skilled in the art of the time of the invention to make

the system powered by battery in order to allow to system when in use with an infusion pump to

be mobile. Furthermore, it would have been obvious for the alarm of Singh's invention to

provide either a visual or audible signal to alert to patient or attending staff to an instance of

infiltration.

Conclusion

3.

Claims 3-5,8,9,17-21 are objected to as being dependent upon a rejected base claim, but

would be allowable if rewritten in independent form including all of the limitations of the base

claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this

Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Page 3

Art Unit: 3763

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lina Kontos whose telephone number is (703) 306-4207. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LRK

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